initially keeps said exposed cancellous bone surface spaced apart from the second joint surface;

using the joint;

whereby the cancellous bone surface initially forms fibroblast which progresses into fibrocartilage as the implant is resorbed so the fibrocartilage effectively replaces the implant during such resorption.--

REMARKS

Claims 1-6, 8-10 and 24-26 are pending in the application.

Claims 1, 5-6 and 21-24 were rejected under 35 U.S.C. §102(b) as being anticipated by Stone et al.

Claims 21-22 were rejected under 35 U.S.C. §102(b) as being anticipated by the Dow Corning Wright Silastic Trapezial Implant H.P. Brochure ("Dow Corning") alone.

Claims 2-3 were rejected under 35 U.S.C. §103(a) as being unpatentable over Stone et al. in view of Delcommune et al.

Claims 8-10 and 25 have been indicated as allowed by the Examiner over the prior art of record.

Applicant appreciates the indication that claims 4 and 7 have been indicated as allowable if placed in independent form.

Formal Matters

The drawings were objected to under 37 CFR 1.83(a) for failing to show every feature of the invention as specified in the claims. However, the stem fitting within a cavity in the medullary canal is shown in FIG 3D. As described on page 7, lines 25-33, a cavity 21 is formed in the medullary canal with power burr 22. The implant 23 is placed within cavity 21 of the medullary canal. Thus, the feature of placing the implant within the medullary canal as recited in claim 7 is supported in the drawings and specification.

Applicant believes that claims 1-6 comply with 35 U.S.C. § 112, first paragraph. For example, the bioresorbable implant being non-porous, as claimed in claims 1 and 7, is consistent with the drawing as originally filed and "non-porous"

Which one? Can't determine non-porosity from a drawing

and "smooth" have been added to the specification. FIG. 2 shows an implant 23 as described by the present invention. The implant has been shaded to indicate a smooth surface without pores. In addition to the drawing, the selected pure polymer of polylactic acid (pg. 5, lines 1-2) has inherent non-porous and homogenous properties. There is no scaffold or matrix within the implant material or structure.

As to the inherent properties of the pure polymer of lactic acid, the specification "need not describe the claimed invention in *ipsis verbis* to comply with the written description requirement" under 35 U.S.C. 112. The test is whether the specification disclosure would reasonably convey to a person having ordinary skill in the art that the applicant had possession of the claimed subject matter. The initial burden is on the Examiner to present evidence or reasons why persons skilled in the art would not recognized in the specification disclosure a description of the invention defined by the claims. See *Ex parte Sorenson*, 3 USPQ2d 1462, 1463 (CCPA 1987), copy enclosed. As the drawing and inherent nature of the implant material disclose a smooth, non-porous surface, no new matter has been added.

Dependent claim 7, indicated allowable, has been rewritten as independent claim 26 so that claim 26 is allowable. (Dependent claim 4 was previously written in independent form as claim 25.)

The Invention

Applicant's invention is directed toward a method for treating a joint using a totally bioresorbable implant. The bioresorbable implant 23 is constructed, for example, from a lactic acid polymer with a smooth, non-porous head 24 and a stem 26 (FIG. 2). The lactic acid polymer and copolymer permits the body to hydrolyze or resorb the implant leaving no trace of the implant.

In the disclosed embodiment and method, the head 14 of the humerus is removed to expose a flat, raw or cancellous bone surface 20. A cavity 21 is power burred into the medullary canal

where stem 26 is implanted. The opposite side of the joint is also resected to form a second cancellous bone surface. The wound is then closed and used under normal conditions. The bioresorbable implant 23 maintains a space between the two cancellous bone surfaces and is permitted to be resorbed by the body through hydrolysis. Friction against the implant causes blood clot to form on the resected cancellous bone surface which later forms into a fibroblast. The fibroblast undergoes fibroplasia and eventually progresses into what appears to be a form of fibrocartilage.

The Cited Art

The patent to Stone discloses a prosthetic articular cartilage device 10 with a porous volume matrix 12 of biocompatible fibers and at least partially resorbable fibers. Some of the fibers may be constructed of collagen with a matrix of polysaccharides. Porous volume matrix 12 is constructed in a cylindrical disk shape with an internal scaffold structure to allow the ingrowth of articular chondrocytes. A conical, rigid base component 20 extends downward from the underside of matrix 12 to impact and anchor the articular cartilage device 10 into the bone 450. Matrix 12 remains flush with the surface of the pre-existing articular cartilage. After the resorbable portion of matrix 12 is degraded, the articular chondrocytes migrate in to form new cartilage. The biocompatible portion of fibers in the implant permanently remains in the joint to provide a support environment for the articular cartilage.

The Dow Corning brochure shows the use of a silicone implant as an interpositional spacer between the trapezium and the first metacarpal joint of the thumb. The implant consists of a head and a short, wide stem which is placed in the bone. The implant is intended as a long term or permanent replacement for the joint structure.

The patent to Delcommune discloses the use of a lactic acid polymer as a biodegradable prosthesis for use in bone surgery.

The Cited Art Distinguished

The Stone patent does not recite the claimed step of selecting a non-porous, totally bioresorbable implant as in the invention of claims 1 and 24. The Stone implant device 10 is constructed of a dry porous volume matrix 12 of biocompatible fibers and partially resorbable fibers (col. 5, lines 47-48). The partially resorbable fibers are presumably resorbed into the body and articular chondrocytes migrate through small pores to occupy the spaces formerly occupied by these fibers. The biocompatible portion permanently remains in the body giving the chondrocytes a support matrix and assumes the form and role of native articular cartilage. This is not a totally bioresorbable implant as is presently claimed in claims 1 and 24. In the present claimed invention, the implant is selected to be a totally bioresorbable. As the implant is hydrolyzed, the body effectively absorbs the entire implant. No trace of the implant remains in the joint area after using the joint for a period of time.

Furthermore, the invention of claim 1 differs from Stone in that fibrocartilage effectively replaces the non-porous, totally bioresorbable implant. As discussed above, the articular chondrocytes migrate to replace the partially bioresorbable portion of the Stone implant. This is not fibrocartilage which completely replaces the implant as in the present invention. After the bioresorbable implant of the claimed invention is placed in the joint surface, the body begins to resorb the implant. A fibroblast develops, apparently from the friction, of the smooth, non-porous implant on the cancellous bone surface and eventually progresses into fibrocartilage. As the implant is completely and totally resorbed, the fibrocartilage remains to replace the implant leaving no traces of the implant. The Stone articular chondrocytes only replace the partially bioresorbable fibers and the biocompatible portion permanently remains in the joint. Thus, Stone does not anticipate a non-porous, totally bioresorbable implant (claims 1 and 24) and fibrocartilage replacing the implant (claim 1). Accordingly, these claims are allowable.

Moreover, it would not have been obvious to use a non-porous, totally bioresorbable implant as recited in claims 1 and 24 in Stone invention. Stone teaches away from using a non-porous, bioresorbable implant. The Stone patent is concerned with providing a permanent cartilage device which assumes the form and role of articular cartilage and provides a scaffold for the regeneration of tissue having the physical characteristics of natural articular cartilage (col. 3, lines 5-9). The implant permanently remains in the joint area and the cartilage forms within the implant, which is the opposite of the claimed invention. Further, there would be no motivation to use a non-porous, totally resorbable implant in Stone since no scaffold would be available for the ingrowth of the chondrocytes and no implant would remain to support the natural articulating joint load forces since it would have been resorbed. Thus, Stone provides no motivation for using a non-porous, bioresorbable implant being totally resorbed and replaced with fibrocartilage. Accordingly, claims 1 and 24 would not have been obvious over Stone alone or in view of the other cited art.

In summary, Applicant's invention would not have been obvious in view of the cited art because the art does not provide for a non-porous, totally bioresorbable implant which provides spacing to allow for fibrocartilage formation which eventually replaces the implant. Moreover, there would be no motivation for replacing the dual component matrix of Stone with a non-porous, totally bioresorbable implant.

CONCLUSION

In light of the amendments to the claims, the application is in condition for allowance and an action to that end is urged. If the Examiner believes a telephone conference

would aid in the prosecution of this case in any way, please call the undersigned at (415) 326-2400.

Respectfully submitted,

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A P P E N D I X

1. (Amended) A method for treating a joint having first and second mating joint surfaces comprising the following steps:
removing at least a portion of the first joint surface so to expose a cancellous bone surface;
selecting a non-porous, totally bioresorbable implant;
placing the bioresorbable implant between and in contact with the first and second joint surfaces so the implant initially keeps said exposed cancellous bone surface spaced apart from the second joint surface;
using the joint; and
whereby the cancellous bone surface initially forms fibroblast which progresses into fibrocartilage as the implant is resorbed so the fibrocartilage effectively replaces the implant during such resorption.

2. The method of claim 1 further comprising the step of selecting the bioresorbable implant made of a polymer of lactic acid.

3. The method of claim 2 wherein the selecting step is carried out by selecting a lactic acid copolymer.

4. The method of claim 1 further comprising the steps of:
estimating the period of time it will take for the fibroblast to progress into fibrocartilage; and
selecting the bioresorbable implant of a size, shape and material according to said period of time.

5. The method of claim 1 further comprising the step of ensuring the exposed cancellous bone surface and the step of ensuring the exposed cancellous bone surface and the surface of the bioresorbable implant placed against said bone surface have complementary surface shapes.

6. (Amended) The method of claim [3] 5 wherein the ensuring step includes the step of selecting curved surface shapes as said complementary surface shapes.

8. A method for treating a substantially non-weight bearing arthritic joint having first and second mating joint surfaces comprising the following steps:
removing at least a portion of the first and second joint surfaces so to expose first and second cancellous bone surfaces;
selecting a bioresorbable implant having first and second implant surfaces corresponding to the first and second cancellous bone surfaces;
placing the first and second implant surfaces of the bioresorbable implant between and against the first and second exposed bone surfaces; and
using the joint;
wherein the cancellous bone surfaces initially form fibroblast which progress into fibrocartilage at each said bone surface as the implant is resorbed, thereby effectively replacing the implant during such resorption.

9. The method of claim 8 wherein the selecting step is carried out by selecting said bioresorbable implant having a generally semi-spherical joint surface as the first implant surface.

10. The method of claim 8 further comprising the steps of:
estimating the period of time it will take for the fibroblast to progress into fibrocartilage; and
selecting the bioresorbable implant of a size and material according to said period of time.

24. (Amended) A method for treating at least one degenerated surface on a cancellous bone, the surface being one of first and second relatively movable surfaces defining a body joint, the method comprising the steps of resecting the bone to form a cancellous bone surface, placing a non-

porous, totally bioresorbable implant between the first and second surfaces to thereby space the surfaces apart, permitting growth of fibroblast on the cancellous surface and conversion of the fibroblast into fibrocartilage, maintaining a spacing between the surfaces during the permitting step and waiting for the body to gradually resorb the implant during the permitting step so that, upon resorption of the implant, the fibrocartilage forms at least one of the movable surfaces.

25. A method for treating a joint having first and second mating joint surfaces comprising the following steps:

removing a least a portion of the first joint surface so to expose a cancellous bone surface;

placing a bioresorbable implant between and in contact with the first and second joint surfaces so the implant initially keeps said exposed cancellous bone surface spaced apart form the second joint surface;

using the joint;

whereby the cancellous bone surface initially forms fibroblast which progresses into fibrocartilage as the implant is resorbed so the fibrocartilage effectively replaces the implant during such resorption;

estimating the period of time it will take for the fibroblast to progress into fibrocartilage; and

selecting the bioresorbable implant of a size, shape and material according to said period of time.

26. (New) A method for treating a joint having first and second mating joint surfaces comprising the following steps:

removing at least a portion of the first joint surface so to expose a cancellous bone surface;

forming a cavity into the medullary canal of the exposed cancellous bone surface;

selecting a non-porous bioresorbable implant having a joint portion configured to fit between the first and second joint surfaces and a stem portion configured to fit within said cavity;

placing the bioresorbable implant between and in contact with the first and second joint surfaces so the implant initially keeps said exposed cancellous bone surface spaced apart from the second joint surface;

using the joint;

whereby the cancellous bone surface initially forms fibroblast which progresses into fibrocartilage as the implant is resorbed so the fibrocartilage effectively replaces the implant during such resorption.